

REMARKS

Claims 1, 5, 13, 14, 29, 35-41 and 47 are presently pending in the case. Claims 52-46 have been cancelled without prejudice or disclaimer. Claims 1, 29, 35-41 and 47 have been amended. The amendments are supported throughout the specification as originally filed. Specific support for some of the amendments is provided below. The other amendments have been made merely for formal reasons and are not intended to change the scope of the claims.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Restriction Requirement

The Examiner required restriction to one of the following allegedly independent or distinct inventions: (I.) Claims 1, 5, 13, 14, 29, 35-41 and 47; and (II.) Claims 42-46. The Examiner then elected Group I for Applicant on the basis of election by original presentation. Though Applicant disagrees with the Examiner's reasoning and traverses the restriction, Applicant has cancelled claims 42-46 in order to expedite prosecution. Applicant reserves the right to pursue claims 42-46 in a continuation or divisional application.

Claim rejections under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1, 5, 13, 14 and 35-41 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Examiner contends that claim 1 contains new matter in its recitation of "a lung deposition is at least 25% over substantially the flow range of the inhaler."

The Examiner's objection to the language in claim 1 is believed improper. However, in order to expedite prosecution, Applicant has amended the language of claim 1 so that it has more literal support in the specification. For example, see page 7 lines 23-25.

The Examiner rejected claims 29, 38-41 and 47 under 35 USC §112, first paragraph, as failing to comply with the written description requirement for the reasons set forth below.

The Examiner contends that claim 29 contains new matter in its recitation of "an emitted dose is at least about 60% ... an interpatient variation in lung deposition is less than about 17% and an intrapatient variation in lung deposition is less than about 6%." Claim 29 has been amended to change "less than about 17%" to "less than 40%" which is supported by Table 6 on page 24. Also, "less than about 6%" has been changed to "does not exceed 6%" which has *ipsis verbis* support at page 24, line 7.

The Examiner contends that claim 38 contains new matter in its recitation of "wherein a difference between lung deposition at about 30 LPM and lung deposition at about 90 LPM is about 11% or less, as measured by FPF_{4+F}." Applicant has amended claim 38 to recite the results of the data presented in Table 4 on page 23 more precisely.

The Examiner contends that claim 39 contains new matter in its recitation of "an intrasubject dose variability is less than about 6% or less." Claim 39 has been amended in similar manner to claim 29 discussed above.

The Examiner contends that claim 40 contains new matter in its recitation of "where a variation in with inhalation flow rate is less than about 20% (*sic*).". Applicant has amended claim 40 to describe the data shown in Figure 2 more precisely.

The Examiner contends that claim 41 contains new matter in its recitation of “wherein an interpatient variation in lung deposition is less than about 17%.” Claim 41 has been amended in similar manner to claim 29 discussed above.

The Examiner contends that claim 47 contains new matter in its recitation of “inhaling the drug composition from the inhaler resulting in lung deposition wherein a variability between patients at a single flow rate is less than about 17%, and a variability with flow rate is less than about 20%.” Claim 47 has been amended in similar manner to claims 29 and 40 above.

Claim rejections under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 1, 5, 13, 14, 29, 35-41 and 47 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner contends that the expression “at least about” is indefinite. Applicant traverses the rejection. In determining the range encompassed by the term “about”, one must consider the context of the term as it is used in the specification and claims of the application. Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1326, (Fed. Cir. 2007). In W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as “exceeding about 10% per second” is definite since range of “about” was clear from the context. In the present context, the range of “about” would be clear to one of ordinary skill in the art from the context of the specification. Since the range of “about” is clear, it follows that the range of “at least about” is also clear since it includes everything that is “about xx” and everything that is greater than that. Therefore, to the extent the rejection still applies following the above amendments, Applicant requests withdrawal of the rejection.

The Examiner contends the claim 1 recitation "a lung deposition is at least 25% over substantially the flow rate range of the inhaler" is confusing. The Examiner does not understand how lung deposition is a different variable than inhaler flow rate and finds it unclear how the two can be tied together. The above amendments to claim 1 are believed to render the rejection moot.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 1, 5, 13, 14, 29, 35-41 and 47 under 35 U.S.C. §03(a) as being unpatentable over U.S. Patent No. 5,934,273 to Anderson et al (hereinafter Anderson et al) in view of PCT Publication WO 96/32096 to Eljamal et al (hereinafter Eljamal et al), U.S. Patent No. 5,855,913 to Hanes et al (hereinafter Hanes et al) and U.S. Patent No. 5,049,389 to Radhakrishnan (hereinafter Radhakrishnan), as evidenced by Swarbrick et al. The rejection is traversed.

Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan, and Swarbrick et al do not render independent claim 1, for example, unpatentable. Claim 1 is to a method for the pulmonary administration of a dry powder composition comprising, *inter alia*, loading the dry powder composition into a passive dry powder inhaler and administering the dry powder composition from the inhaler to the respiratory tract of a patient, wherein the emitted dose is at least 60% and the lung deposition is greater than 25% over a range of flow rates from 10 to 60 liters per minute. Anderson et al does not disclose the method as set forth in claim 1. Anderson et al discloses administering a dry powder composition using a Turbuhaler dry powder inhaler. As can be seen in Applicant's Example 2, the present invention is superior to compositions, such as Anderson et al's that are administered with a Turbuhaler. As shown in Table 2, lung deposition using a Turbuhaler is 15% at a flow rate of 35 liters per minute. Thus, the Turbuhaler administered composition does not provide a lung deposition of greater than 25% for flow rates from 10 to 60 liters per minute. Accordingly, Anderson et al does not disclose all features of claim 1 and does not render the claim unpatentable.

The other references do not make up for the deficiencies of Anderson et al. Anderson et al does not disclose a pulmonary administration using a passive dry powder inhaler wherein an emitted dose of at least 60% is achieved and lung deposition is greater than 25% for over a range of flow rates from 10 to 60 liters per minute. Eljamal et al, Hanes et al, Radhakrishnan, and Swarbrick et al do not make up for this deficiency in Anderson et al. Eljamal et al does not disclose administering a dry powder using a passive dry powder inhaler where 60% emitted dose is achieved and where lung deposition is greater than 25% over the range of 10 to 60 liters per minute. To the contrary, Eljamal teaches a powder where dispersibility is increased by formulating the powder with a water-soluble polypeptide. Eljamal et al teaches the use of an active dry powder inhaler rather than a passive one (see page 14 lines 1-28). Even then, Eljamal et al does not teach an emitted dose and lung deposition as required by claim 1. Hanes et al also fails to teach a powder administered in a passive dry powder inhaler and achieving the emitted dose and lung deposition as claimed. Radhakrishnan et al teaches the delivery of liposomes by nebulization and does not teach a passive dry powder inhaler that delivers a powder with the claimed emitted dose and lung deposition.

Thus, no reference or combination of references arrives at an administration as recited in claim 1. Accordingly, the Examiner has not established a prima facie case under 35 U.S.C. §103(a).

For at least these reasons, claim 1 is not properly rejectable under 35 U.S.C. §103(a) as being unpatentable over Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan and Swarbrick et al. The modification that would be necessary is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have been motivated to modify Anderson et al in a manner that would result in the invention of claim 1, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 1 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 5, 13, 14 and 35-41, which depend from claim 1 and are not rendered unpatentable by Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan and Swarbrick et al for at least the same reasons as claim 1.

Independent claim 29 is not rendered unpatentable by Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan, and Swarbrick et al, either. Claim 29 is to a method for the pulmonary administration of a dry powder composition comprising, *inter alia*, providing a dry powder composition, loading the dry powder composition into a passive dry powder inhaler, and administering the dry powder composition from the inhaler to the respiratory tract of a patient, wherein the fine particle fraction emitted from the inhaler is at least 60% and wherein a lung deposition is at least 25%. Anderson et al discloses administering a dry powder composition using a Turbuhaler dry powder inhaler. However, there is no evidence to suggest that the administered powder from Anderson et al would have a fine particle fraction of at least 60% and/or a lung deposition of at least 25%. Accordingly, Anderson et al does not disclose all features of claim 29 and does not render the claim unpatentable.

The other references do not make up for the deficiencies of Anderson et al. Anderson et al does not disclose a pulmonary administration using a passive dry powder inhaler wherein the fine particle fraction is at least 60% and lung deposition of at least 25%. Eljamal et al, Hanes et al, Radhakrishnan, and Swarbrick et al are not relied on to make up for this deficiency in Anderson et al, nor do they, as discussed above. Accordingly, no reference or combination of references arrives at an administration as recited in claim 29. Accordingly, the Examiner has not established a *prima facie* case under 35 U.S.C. §103(a).

For at least these reasons, claim 29 is not properly rejectable under 35 U.S.C. §103(a) as being unpatentable over Anderson et al, Eljamal et al, Hanes et al,

Radhakrishnan and Swarbrick et al. The modification that would be necessary is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have been motivated to modify Anderson et al in a manner that would result in the invention of claim 29, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 29 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 29 under 35 U.S.C. §103(a).

Independent claim 47 is not rendered unpatentable by Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan, and Swarbrick et al, either. Claim 47 is to a method for inhalation of a dry powder drug comprising, *inter alia*, inhaling the drug composition from a passive dry powder inhaler resulting in lung deposition wherein a variability with flow rate of 30 L/min as compared with a flow rate of 90 L/min is less than 20%. Anderson et al does not disclose administration of a dry powder drug with a passive dry powder inhaler. The balance of the references does not make up for Anderson's deficiency. For example, Eljamal et al teaches an active inhaler, as discussed above. Furthermore, no reference or combination of references teaches the flow rate independence as recited in claim 47. Thus, the Examiner has failed to establish a *prima facie* case under 35 U.S.C. §103(a).

For at least these reasons, claim 47 is not properly rejectable under 35 U.S.C. §103(a) as being unpatentable over Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan and Swarbrick et al. The modification that would be necessary is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have been motivated to modify Anderson et al in a manner that would result in the invention of claim 47, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 47 is

allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 47 under 35 U.S.C. §103(a).

Claim rejections under judicially created doctrine of Double Patenting

The Examiner provisionally rejected claims 1, 5, 13, 14, 29, 35-41 and 47 and under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent Application No. 10/141,219 in view of Anderson et al and Hanes et al.

The Examiner provisionally rejected claims 1, 5, 13, 14, 29, 35-41 and 47 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent Application No. 11/187,757 in view of Anderson et al and Hanes et al.

The Examiner rejected claims 1, 5, 13, 14, 29, 35-41 and 47 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent No. 7,306,787 in view of Anderson et al.

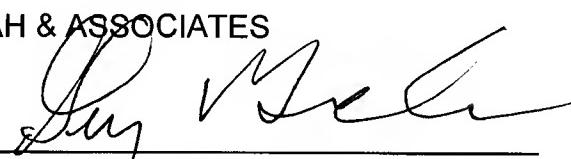
The double patenting rejections will be taken up and the appropriateness of filing a terminal disclaimer will be determined upon the indication of otherwise allowable claims.

Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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